1 800 CONTACTS®
CONTACTS.COM

January 13, 2003 2029 '04 JAN 13 P2:58

Dockets Management Branch
U.S. Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20857

Re: Docket # 2003P-0291 ("National Contact Lens Enforcement Petition")

Dear Sir or Madam:

I am writing on behalf of 1-800 CONTACTS, Inc. ("1-800") to alert the Food and Drug Administration ("FDA") that the above-referenced petition is yet another attempt by a minority of self-interested eye care practitioners ("ECPs") to present your agency with old and repeatedly discredited claims of increased health complications associated with: (1) purchasing contact lenses from alternative retailers (i.e., non-ECPs such as mail order, pharmacy or Internet sellers), and (2) the "presumed" or "passive" verification method that many such retailers utilize to verify consumer prescriptions.

As discussed more fully below, the contact lens industry is unusual in the sense that ECPs are among the few health care practitioners that have been allowed to sell the products that they prescribe. As a result, EPCs have a powerful economic motivation to make unsubstantiated health claims against their alternative retailer competitors. They also have a long history of making such unsubstantiated health claims. Indeed, the very health claims they advance in this petition have been rejected repeatedly in both the litigation, regulatory and legislative contexts, most recently by Congress which passed the Fairness to Contact Lens Consumers Act ("FCLCA"), P.L. 108-164, to make it easier for consumers to purchase contact lenses from alternative retailers and to allow such retailers to utilize the "presumed" or "passive" verification method for verifying consumer prescriptions.

Conspicuously missing from the instant docket is any support from consumers, consumer groups or public officials. Even the major ECP associations themselves (e.g., the American Optometric Association, the American Academy of Ophthalmology, various state optometric associations) recently have abandoned such health claims by either endorsing or agreeing not to oppose the FCLCA or state legislation which specifically enables consumers to purchase lenses from alternative retailers and allows such retailers to utilize "presumed" or "passive" verification to verify consumer prescriptions.

Also missing from the instant docket is any valid clinical or scientific data comparing the safety of purchasing lenses from ECPs and alternative retailers that might support the ECP petitioners' repeatedly discredited claims. Although the ECP petitioners characteristically point to self-serving anecdotal evidence from ECPs that a relatively small number of contact lens wearers have experienced health complications, *such complications have no relationship whatsoever to where the consumers purchased their contact lenses or the prescription verification method utilized by their retailer.*

2003P-0291 C 61

66 East Wadsworth Park Drive | 3rd Floor | Draper, Utah 84020 | T 801 924 9800 | F 801 924 9905

The ECP petitioners' criticism of the FDA for not addressing the prescription verification practices of alternative retailers (a task Congress specifically has given to the Federal Trade Commission) is simply unfounded. Indeed, the real issue is not whether the FDA should address prescription verification practices of alternative retailers but whether ECPs should be restricted from selling the products they prescribe so that their health care decisions are based on the consumer's best interest rather than the ECP's financial interest in retailing prescription items.

1. There Is No Evidence Of Increased Health Complications Associated With Purchasing Contact Lenses From Alternative Retailers.

Although the ECP petitioners claim not to challenge the safety of purchasing contact lenses from alternative retailers, their alleged health claims focus solely on their alternative retailer competitors. ECPs have long attempted to impede competition from alternative retailers by arguing or implying that there are increased health complications associated with purchasing contact lenses from such retailers. These health claims have been repeatedly discredited.

During the 1990s, ECPs vigorously opposed both legislation and regulations that would have required them to give patients a copy of their contact lens prescription on the ground that purchasing contact lenses from alternative retailers posed increased health risks. The Attorneys General of numerous states investigated these health claims and concluded that:

> Purchasers from alternative channels have had no greater ocular health problems than purchasers from eye-care practitioners. Our multi-state investigation has failed to reveal any study showing any correlation between compromised ocular health and receipt of lenses through alternative channels.

See Tab 1, Comments of Attorneys General to FTC's Request for Comments concerning Ophthalmic Practice Rules, at p. 8.[1] To the contrary, the Attorneys General found that alternative retailers actually *increased* consumer safety because consumers were more apt to replace their lenses more frequently when offered easier access to, and lower prices for, contact lenses from such retailers. *Id.*, at p. 7.

Likewise, 32 State Attorneys General and a national class of consumers sued the American Optometric Association ("AOA") and various individual ECPs for conspiring to impede competition from alternative retailers by, among other things, falsely claiming increased health risks from purchasing contact lenses from alternative retailers. *In re Disposable Contact Lens Antitrust Litigation*, MDL 1030 (M.D. Fla, Jacksonville Division) ("MDL 1030").[2] Plaintiff States found that ECPs and their associations disseminated knowingly fabricated or misleading survey data to the FDA and others purporting to show significant health risks associated with

[1] The participating states included Alaska, Arizona, Arkansas, California, Connecticut, Delaware, Florida, Illinois, Iowa, Maryland, Michigan, Minnesota, New York, Ohio, Pennsylvania, West Virginia and Wisconsin.

[2] Plaintiff States included Alabama, Alaska, Arizona, Arkansas, California, Connecticut, Delaware, Florida, Idaho, Illinois, Iowa, Kansas, Louisiana, Maine, Maryland, Massachusets, Michigan, Minnesota, Missouri, Nevada, New Jersey, New York, North Carolina, North Dakota, Ohio, Oregon, Pennsylvania, Texas, Utah, Virginia, West Virginia and Wisconsin.

purchasing contact lenses from alternative retailers. *See* Tab 2, Plaintiff States' Consolidated Statement of Facts in MDL 1030, at pp. 56-60. Indeed, the survey's own author testified that he did not consider it a scientifically valid survey or a fair and honest representation of the actual state of medical affairs that it purported to represent. *Id.*, at p. 60. Worse yet, discovery revealed that ECPs and their associations actually considered doing a legitimate study comparing the safety of purchasing contact lenses from alternative retailers and ECPs and rejected the idea in part due to fear that the results would not support their claims. *Id.*, at p. 60, n. 183.

The AOA and other ECP defendants ultimately entered into settlements in May 2001 whereby they agreed to certain injunctive terms. This injunction provided, among other things, that:

> The AOA shall not represent directly or indirectly that the incidence or likelihood of eye health problems arising from the use of replacement disposable contact lenses is affected by or causally related to the channel of trade from which the buyer obtains such lenses. Specifically, the AOA shall not represent directly or indirectly that increased eye health risk is inherent in the distribution of replacement disposable contact lenses by mail order, pharmacies, or drug stores. This paragraph shall not prohibit the AOA from making such representations where such representations are supported by valid, clinical or scientific data.

See Tab 3, Settlement Agreement in MDL 1030, at ¶5(h).

Since this injunction against making unsubstantiated health claims became effective in May 2001, the State Attorneys General repeatedly have asked the AOA to produce any valid clinical or scientific data of increased health complications associated with purchasing contact lenses from alternative retailers but no such data has ever been produced. *See* Tab 4, Testimony of Robert L. Hubbard, Chair of Plaintiff States' Steering Committee in MDL 1030, dated September 9, 2003, at pp. 7-10. Indeed, the State Attorneys General have never seen any such evidence of increased health complications despite the fact that alternative channels have been selling contact lenses now for well over two decades. *Id.*, at p. 9, n. 18. In testimony before the House Subcommittee on Commerce, Trade and Consumer Protection, Mr. Hubbard explained:

> The States have a lot of experience in this industry. * * * We have over time become quite skeptical of the health care claims that are made about the kind of difficulties that consumers face and the justifications for those restraints on health care. We have asked for and never gotten the kind of evidentiary support that we would find necessary to give those health care claims credence. * * * [H]ealth care claims have been made ever since competition reared its head in this industry. And we would have expected there to have been a manifestation of those concerns and better documentation of them by now. * * * [A]s I mentioned before,

there's no documented harm from consumers going to alternative [retailers], instead of their ECPs.

See Tab 5, Excerpts from Hearing before House Subcommittee on Commerce, Trade and Consumer Protection dated September 12, 2003, at pp. 4-5.

The complete absence of evidence of increased health complications associated with purchasing contact lenses from alternative retailers is consistent with the experience of 1-800 as an alternative retailer. 1-800 has filled nearly 10 million orders to over 3 million customers since its inception in 1995. Not a single customer has filed a claim against it for any reason, let alone a health incident. Although ECPs have disseminated self-serving anecdotal evidence from ECPs that a relatively small number of contact lens wearers have experienced health complications, those complications have no relationship whatsoever to where the consumers purchased their contact lenses or the prescription verification method utilized by their retailer. Indeed, ECP petitioners' characteristically avoid any comparison of health complications from lenses purchased from ECPs with lenses purchased from alternative retailers. The relatively few health incidents that have been reported in the press generally have involved purchases from ECPs rather than an alternative retailer like 1-800.

Given ECPs' powerful economic motivation to make unsubstantiated health claims against their alternative retailer competitors, their long history of making such unsubstantiated health claims, their refusal to do a legitimate study to determine whether such claims have any validity, and the absence of any support for such claims from anyone other than a minority of self-interested ECPs, the FDA should reject these old and repeatedly discredited claims.

2. There Is No Evidence Of Increased Health Complications Associated With Alternative Retailers Utilizing The "Presumed" or "Passive" Verification Method For Verifying Consumer Prescriptions.

ECP petitioners argue that alternative retailers should not be allowed to sell contact lenses to consumers without requesting and receiving an affirmative response from the prescribing ECP approving the sale, also known as "affirmative" or "positive" verification. These petitioners claim, without support, that there are increased health complications associated with the "presumed" or "passive" verification method for verifying consumer prescriptions. Under this method, the alternative retailer communicates to the consumer's ECP the exact prescription specifications received from the consumer and informs the ECP that it will complete the sale based on this prescription unless the ECP advises it within a reasonable time period that such prescription is expired or incorrect. These unsubstantiated health claims regarding "presumed" or "passive" verification also have been repeatedly rejected, most recently by Congress which passed the FCLCA precisely to allow alternative retailers to utilize the "presumed" or "passive" verification method nationwide.

The contact lens industry is unusual in the sense that ECPs are among the few practitioners who are allowed to sell the products that they prescribe. As a result of this inherent conflict of interest, many ECPs refuse either to release or verify prescriptions, even where the law expressly requires them to do so, in order to force consumers to purchase contact lenses from them rather than an alternative retailer. When an alternative retailer requests an ECP (its

principal competitor) to release or verify a consumer's prescription, its request is tantamount to one *retailer* asking *another retailer* for permission to sell to the latter's customer. Not surprisingly, many ECPs refuse to cooperate with such prescription verification requests by evading, ignoring or otherwise refusing to respond *affirmatively* to them.

In response to the widespread refusal of California optometrists to respond affirmatively to its prescription verification requests, 1-800 initiated the presumed verification method in California in 1998 with the approval of the California Medical Board.[3] Although this practice initially spawned litigation with California optometrists, who argued that affirmative verification was the only safe and permissible method for verifying contact lens prescriptions, such litigation ultimately settled with an agreement that expressly allowed presumed verification with a waiting period of three business hours. *Craig S. Steinberg, et al. v. 1-800 CONTACTS*, Los Angeles Superior Court Case No. BC 194243.

In 2002, California passed legislation that essentially codified the presumed verification agreement in place there since 1998. *See* Tab 6, California AB 2020, at 7:35-8:13, codified at Cal. Bus & Prof. Code § 2546.6(a) ("A prescription shall be deemed confirmed [where] ... the prescriber fails to communicate with the seller [within approximately 8 business hours] after the seller requests confirmation."). This presumed verification law was supported even by the California Optometric Association ("COA") which indicated that "it supports safe and responsible patient access to contact lens prescriptions as well as the safe and responsible filling of those prescriptions" and that "[this law] strikes a reasonable balance between access and accountability." *See* Tab 7, COA letter to the Honorable Lou Correa dated July 15, 2002.

Likewise, other states began to approve expressly the presumed verification method for verifying prescriptions. See, e.g., Miss. Stat., HB 906, at Section 14 ("If confirmation of the verification request for the drug or medical device is not received within one (1) hour following the request, all information contained in the request, including the fact that the prescription has not expired, shall be presumed accurate, and the provider shall be authorized to dispense pursuant to the prescription); Utah Code Ann. § 58-16a-801(1)(e)(ii) (expressly approving passive verification method for verifying contact lens prescriptions). Like California, Utah's presumed verification law was supported even by the Utah Optometric Association.

Amid continued unsubstantiated health claims from some ECPs regarding presumed verification, FTC staff submitted written comments and testimony in a regulatory proceeding in Connecticut which expressly supported the presumed verification method for

---

[3] In an attempt to operate in this nearly impossible environment, 1-800 CONTACTS and a number of other alternative retailers previously had employed a "good faith attempt" or "best efforts approach" to verifying consumer prescriptions. Under this approach, the alternative retailer would make a good faith attempt to contact the consumer's ECP (usually by telephone) to verify the prescription but would proceed with the sale if it was unable to communicate successfully with the prescriber. This approach should not be confused with "presumed" or "passive" verification which requires that the alternative retailer successfully communicate to the consumer's ECP (usually by facsimile): (1) the exact prescription specifications received from the consumer, (2) notice that the sale will proceed based on this prescription unless the ECP advises it within a certain time period that such prescription is expired or incorrect, and (3) the specific time period after which the prescription will be presumed valid absent a response. In contrast to the "best efforts approach," the alternative retailer utilizing presumed verification may not proceed with the sale if it is unable to communicate such information successfully to the consumer's ECP and allow the ECP a reasonable opportunity to respond.

verifying consumer prescriptions. Drawing upon their significant expertise concerning regulation and competition and their considerable experience with the eye care industry in particular over the past three decades, FTC staff explained that "[t]he way in which the prescription requirement is interpreted and enforced could have a substantial impact on competition" and emphasized the importance of adopting "the most pro-competitive approach consistent with the protection of consumers' health." See Tab 8, Comments of the Staff of the FTC, In re Declaratory Ruling Proceeding, Connecticut Board of Examiners for Opticians (March 27, 2002) ("FTC Comments"), at p. 12. After consideration of both the competitive aspects of prescription verification and the related health arguments, FTC staff concluded that:

> Consumers who wish to order lenses by phone, mail or Internet can either mail in, call in, fax or provide in electronic form their prescription information to the lens seller. The lens seller can contact the eye care provider in the same ways, if prescription verification is necessary. Likewise, a valid prescription, communicated to the seller by the patient, *can be presumed verified if the doctor is contacted and given sufficient opportunity to correct any errors*."

Id. (emphasis added). *See also* Tab 9, Hearing Testimony of Ted Cruz, FTC (June 12, 2002), at 208:15-22 ("given the significant possibility that the individual optometrist might refuse to affirmatively confirm, it would be a reasonable determination for this Board to make that a prescription can be presumed received if the customer gives that information to the seller and the seller contacts the issuing optometrist and gives [the optometrist] a reasonable opportunity to correct any errors").

During this same time period, these unsubstantiated health claims became the subject of extensive litigation between 1-800 CONTACTS and Johnson & Johnson Vision Care, Inc. ("J&J"). At issue was J&J's refusal to abide by an injunction in MDL 1030 requiring it to supply lenses to 1-800 on the basis that the presumed verification method employed by 1-800 violated FDA regulations and posed unnecessary health risks. Unable to point to any FDA regulation that expressly required contact lens sellers to receive an affirmative response from the consumer's ECP approving the sale (i.e., affirmative verification), J&J relied entirely on a mischaracterization of a statement formerly on the FDA's website indicating that a seller who checks with the consumer's ECP and receives a verbal okay has obtained a valid prescription. Contrary to the assertions of J&J and some ECPs, this former statement did not purport to prohibit other methods a seller might utilize to verify prescriptions (e.g., presumed verification)

or preempt state laws allowing such verification methods.[4] Following substantial discovery and an extended evidentiary hearing during the Fall of 2002, the parties, at the court's direction, entered into a settlement whereby J&J agreed to supply its lenses to 1-800 CONTACTS under a presumed verification system with a waiting period of eight business hours except in a few states which expressly required positive verification.

Facing the threat of increased competition from alternative retailers utilizing presumed verification (which method eliminates the ECP's ability to prevent sales to consumers with valid prescriptions simply by ignoring or evading verification requests), the AOA launched an all out effort to cripple alternative retailers by urging each state optometric association to introduce positive verification legislation in its respective state based on supposed "health concerns." *See* Tab 12, Bulletin No. 43 from AOA State Government Relations Center, at pp. 2-3 ("[B]ecause the AOA believes that the eye health of patients should not be placed in unnecessary jeopardy, the AOA strongly encourages states to pursue positive verification laws in order to protect the ocular health of the public."). Although the State Attorneys General acknowledged the AOA's right to petition for positive verification legislation, they made clear that the AOA could not do so by making unsubstantiated health claims in violation of the injunction in MDL 1030. *See* Tab 13, State Attorneys General letter to AOA Counsel Edward C. LaRose dated September 4, 2003, at p. 2 ("the AOA may not seek to justify "positive" verification as premised on a health care justification, except when those claims "are supported by valid, clinical or scientific data").

> Unlike physicians, ECPs both prescribe and sell contact lenses. Thus, "positive" verification accords the ECP the right to veto with silence each and every sale to consumers who patronize that ECP. The ECP might "exercise" the veto by silence made possible by "positive" verification requirements for anticompetitive reasons or simply because the ECP is disorganized, inefficient, and/or unresponsive to consumers. An ECP's ability to veto a sale with silence when "positive" verification is used can reward the anticompetitive, unresponsive, and inefficient ECP and deprives consumers of the value and competition provided by alternative channels.

---

[4] The former FDA statement, which was part of a guide for purchasers of contact lenses on the Internet, noted that "some Internet sites ask for information about your doctor so that they may check the prescription with your doctor. If they do check with your doctor and receive a verbal okay, they comply with the Federal prescription device regulation. If the Company does not check, then they have not obtained a valid prescription." *See* Tab 10, Buying Contact Lenses on the Internet, by Phone or by Mail: Questions and Answers (updated as of 5/21/01), formerly available at http://www.fda.gov/cdrh/consumer/buycontactqa.html, at pp. 1-2. Shortly after resolution of the litigation between J&J and 1-800, the FDA revised its website to make clear that (as of the time of the revision) state law determined which prescription verification methods a seller could employ. *See* Tab 11, Buying Contact Lenses on the Internet, by Phone or by Mail: Questions and Answers (updated as of 11/27/02), available at http://www.fda.gov/cdrh/consumer/buycontactqa.html, at pp. 1-2 ("State laws vary greatly concerning the kind of verification that is required. Internet sites should comply with applicable State requirements concerning verification of prescriptions for contact lenses."). We note that this statement will now require further revision in light of the recent enactment of the FCLCA, which sets forth a uniform national standard for prescription release and verification.

> Your letter does not assert and my understanding is that the AOA does not assert that the need for "positive" verification is "supported by valid, clinical or scientific data. We would be surprised if the AOA changed its position on this topic and repeat our request that you provide to us any such data if you or the AOA become aware of such data.

Id., at pp. 3-4 (footnotes omitted). Not surprisingly, the AOA was unable to produce any valid, clinical or scientific data showing increased health complications associated with alternative retailers utilizing the presumed or passive verification method for verifying consumer prescriptions.

Throughout 2003 the topic of presumed verification was debated in Congress. A number of different bills were introduced seeking to guarantee consumers the right to purchase contact lenses from alternative retailers and to address the widespread refusal of ECPs to respond to requests to release or verify consumer prescriptions. Despite unsubstantiated health claims from some ECPs, broad support emerged for presumed verification from consumers, consumer groups, State Attorneys General, alternative retailers and others. *See, e.g.*, Tab 14, Testimony of Peggy Venable, Director, Texas Citizens for a Sound Economy, dated September 9, 2003, at p. 5 ("We support a passive verification process in which the optometrist has the opportunity and responsibility to review the prescription prior to it being filled by the retailer of the consumer's choice. If the optometrist or ophthalmologist fails to respond within a reasonable period of time, then the retailer should be able to assume the prescription is valid and fill the consumer's order."); Tab 15, Testimony of Ami V. Gadhia, Assistant Legislative Counsel, Consumers Union, dated September 9, 2003, at p. 5 ("Consumers Union believes that as long as a vendor has a reason to believe that the prescription is still valid ... then passive filling should be appropriate."); Tab 5, Testimony of Robert L. Hubbard, Chair of Plaintiff States' Steering Committee in MDL 1030, dated September 9, 2003, at p. 9 (recommending "passive verification" and noting that in MDL 1030 "we took the position as a group of [32] States that passive verification was sufficient").

With regard to ECP claims that presumed verification posed increased health risks, the State Attorneys General representative testified:

> Certainly the ocular health of consumers is something that interests the attorneys generals. And we certainly were asked by our bosses to make sure that the position that we were taking in the litigation was not risking the ocular health of consumers. And we took those concerns very seriously. We always, when we had an optometrist under oath, said "what evidence of ocular health risks are there? Can you document that?" That was always what we asked. And we never got documentation of those risks.
>
> We take ocular health concerns very seriously. And we looked at those in a lot of depth. We don't profess to be medical doctors. But we think that the passive verification [method] fulfills the purposes that consumers are entitled to."

Id., at pp. 7-8.

The FCLCA was introduced on September 23, 2003 to establish a national uniform standard for prescription release and verification. *See* Tab 16, H.R. 3140. It requires, among other things, that ECPs release and verify prescriptions both to consumers and to other contact lens sellers. *Id.*, H.R. 3140, Section 2(a). It also requires contact lens sellers to verify the consumer's prescription and provides that a prescription shall be presumed valid if "[t]he prescriber fails to communicate with the seller within 8 business hours, or a similar time as defined by the Federal Trade Commission, after receiving from the seller [a proper verification request]." *Id.*, H.R. 3140, Section 4(a) & Section 4(d)(3). It also provides that the FTC shall enforce the Act consistent with the FTC Act. *Id.*, H.R. 3140, Section 9(b).[5] Finally, it directs the FTC to undertake a study to examine the competitive impact of other ECP practices, such as prescribing lenses that are available for sale only by ECPs. *Id.*, H.R. 3140, Section 10(a).

The FCLCA received widespread support from consumers, consumer groups, State Attorneys General, alternative retailers and others. Despite the fact that it had previously claimed, without support, that presumed verification presented unnecessary health risks, even the AOA itself endorsed the FCLCA. *See* Tab 17, AOA letter to the Honorable Richard Burr dated September 23, 2003. Other major ECP groups, including the American Academy of Ophthalmology ("AAO"), likewise made clear that they would not oppose the FCLCA. *See* Tab 18, AAO letter to the Honorable Robert F. Bennett dated November 6, 2003. Not surprisingly, The FCLCA overwhelmingly passed the House of Representatives by a vote of 406 to 12 on November 19, 2003 and passed the Senate without opposition the following day. The FCLCA was signed into law by President Bush on December 6, 2003 and will become effective February 4, 2004. *See* P.L. 108-164.

The ECP petitioners provide no clinical or scientific data to support their health claims regarding presumed verification. Rather, they cite the same self-serving anecdotal evidence and regurgitate the same old arguments that have been thoroughly vetted and overwhelmingly rejected in both the litigation, regulatory and legislative contexts. Given ECPs' powerful economic motivation to make unsubstantiated health claims against their alternative retailer competitors, their long history of making such unsubstantiated health claims, their refusal to do a legitimate study to determine whether presumed verification in fact causes increased health complications, and the absence of any support for such health claims from anyone other than a minority of self-interested ECPs, the FDA should summarily reject this Citizen Petition. Indeed, it appears that petitioners may have violated FDA regulations by failing to include "information known to the petitioner which is unfavorable to the petition" as required by 21 C.F.R. § 10.30(b).

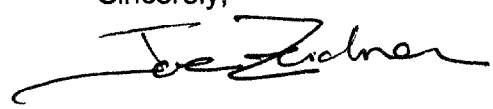
---

[5] ECP petitioners criticize the FDA for failing to enforce supposed violations of prescription verification laws on the basis that "[t]he FDA is the only government agency that has the power to regulate all interstate sales of contact lenses." Although the FDA determines whether a device requires a prescription, until recently the contents of a valid prescription, the rules governing contact lens sellers and general enforcement of prescription device sales was left to the states. See Tab 11, FDA website, at pp. 1-2 (stating that the definition of a contact lens prescription "depends on the state where your doctor practices" and that "[s]ince individual states have different licensing requirements for optical dispensers, enforcement of prescription device sales has usually been left to State authorities."). With the enactment of the FCLCA, the obligation of contact lens sellers to verify consumer prescriptions will be enforced by the FTC. Thus, ECP petitioners' criticism of the FDA is misplaced.

In sum, the real issue is not whether the FDA should address prescription verification practices of alternative retailers (a task Congress specifically has given to the FTC) but whether ECPs should be allowed to continue selling the products that they prescribe. Indeed, it is ironic that ECP petitioners complain about alternative retailers' purported non-compliance with prescription verification requirements when numerous lawsuits, extensive multi-district litigation, nationwide injunctions, FTC studies and repeated legislation all have been necessitated by the widespread misconduct of ECPs and their failure to comply with applicable prescription release and verification requirements. If the ECPs' inherent conflict of interest were eliminated by restricting their ability to sell the products that they prescribe, alternative retailers would have little difficulty securing verification of consumer prescriptions, and health care decisions could be made based on the consumer's best interest rather than the ECP's financial interest in retailing prescription items.

Thank you for your consideration of these comments. Please do not hesitate to contact us if you have any questions.

Sincerely,



R. Joe Zeidner
General Counsel

JZ/gtv

cc: Mark McClellan, M.D.
Dan Troy, J.D.
A. Ralph Rosenthal, M.D.